Review 2: "Safety and efficacy of the ChAdOx1 nCoV-19 (AZD1222) Covid-19 vaccine against the B.1.351 variant in South Africa"

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RR:C19 Evidence Scale rating by reviewer:

- **Potentially informative.** The main claims made are not strongly justified by the methods and data, but may yield some insight. The results and conclusions of the study may resemble those from the hypothetical ideal study, but there is substantial room for doubt. Decision-makers should consider this evidence only with a thorough understanding of its weaknesses, alongside other evidence and theory. Decision-makers should not consider this actionable, unless the weaknesses are clearly understood and there is other theory and evidence to further support it.

Review:

The paper by Madhi et al., entitled Safety and efficacy of the ChAdOx1 nCoV-19 (AZD1222) Covid-19 vaccine against the B.1.351 variant in South Africa explored an important problem that the COVID-19 vaccine is facing at this time.

The paper has multiple strengths mainly because the authors conducted a randomized multicenter, double-blinded controlled trial. In general, the results are well-presented, however, some mistakes must be corrected such as the lack of figure 1. For this reviewer, it is not appropriate to include data from other cohorts for the shared analyzes, as presented in figure 2.

The safety results of the ChAdOx1-nCoV vaccine are very promising and show that it can be applied without risk to the population. Additionally, the absence of reactogenicity was observed after the 2nd dose.

The appropriate evaluation of T-helper lymphocyte cell responses is really important to perform an adequate analysis in the South African vaccinee population since the data included in the paper belongs to a different cohort from another country (unpublished data on a subset of 17 ChAdOx1-nCoV-19 recipients from the UK).

For this reviewer, it is very important that the paper shows that ChAdOx1-nCoV had no efficacy against non-hospitalized mild to moderate Covid-19 mainly due to the B.1.351 variant. The lack of efficacy being specific to the B.1.351 variant, is supported by primary/secondary outcomes and by PSVNA and LVNA.

The conclusion of the paper adequately reflects the results presented.